DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Delegation of Authority

Notice is hereby given that, under the authority vested in me by the Secretary, Department of Health and Human Services, I have redelegated to the Commissioner, Administration on Children, Youth and Families, with the authority to further redelegate to the Director, Family Youth Services Bureau, the authority to approve/disapprove cooperative research or demonstration projects under Section 1110 of the Social Security Act, and as amended hereafter, when such projects pertain to the abstinence education activities referenced in Public Law 108–447 at Title II, Division F.

This delegation excludes the authority to submit reports to Congress. Further, this delegation shall be exercised under the Department's existing delegation and policy on regulations and under financial and administrative requirements applicable to all Administration for Children and Families authorities. In addition, where all or part of any research or demonstration project is wholly financed with Federal funds made available under section 1110 of the Social Security Act, without any State, local, or other non-Federal financial participation, that project must be approved by the Secretary of Health and Human Services.

I have ratified any actions taken by the Commissioner, Administration on Children, Youth and Families, or any other Administration on Children, Youth and Families officials, which, in effect, involved the exercise of this authority prior to the effective date of this delegation. This delegation was effective on the date of signature.

Dated: January 21, 2005.

Wade F. Horn,

Assistant Secretary for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0040]

Authorization of Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax by Individuals at Heightened Risk of Exposure Due to Attack With Anthrax; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for Anthrax Vaccine Adsorbed (AVA) for prevention of inhalation anthrax for individuals between 18 and 65 years of age who are deemed by the Department of Defense (DoD) to be at heightened risk of exposure due to attack with anthrax. FDA is issuing this Authorization under the Federal Food, Drug, and Cosmetic Act (the act), as requested by DoD. The Authorization contains, among other things, conditions on the emergency use of AVA. The Authorization follows the determination by DoD that there is a significant potential for a military emergency involving a heightened risk to U.S. military forces of attack with anthrax. On the basis of such determination, Secretary of Health and Human Services Tommy G. Thompson (the Secretary) declared an emergency justifying the authorization of the emergency use of AVA. The Authorization, which includes an explanation of the reasons for its issuance, is reprinted in this Notice.

DATES: The Authorization is effective as of January 27, 2005.

ADDRESSES: Submit written requests for single copies of the Emergency Use Authorization to the Office of Counterterrorism Policy and Planning (HF–29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Margaret O'K. Glavin, Office of Counterterrorism Policy and Planning (HF–29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4067.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the act (21 U.S.C. 360bbb–3), as amended by the Project BioShield Act of 2004 (Public Law 108–276), allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product during a declared emergency involving a heightened risk of attack on the public or U.S. military forces. With this EUA authority, FDA can help assure that medical countermeasures may be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by such agents, when there are no adequate, approved, and available alternatives to protect the American people and the U.S. military.

Section 564(b)(1) of the act provides that, before an EUA may be issued, the Secretary must declare an emergency based on one of the following grounds:

(1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents;

(2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or

(3) a determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act (PHS Act) that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.

Once the Secretary has declared an emergency justifying an authorization under section 564 of the act, FDA may authorize the emergency use of a drug, device, or biological product if the agency concludes, based on the information and data available to the agency, that the statutory criteria of section 564(c) of the act are satisfied. Under section 564(h)(1) of the act FDA is required to publish in the **Federal Register** notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. The explanation may include a summary of data submitted to FDA in an application